REMARKS

Upon entry of the present Amendment, claims 36, 37, 39, 40, 42-44, 47, 48, 50, 53, 57, 69, 71-77 and 79 will be pending. Claims 1-35, 38, 41, 45, 46, 49, 51, 52, 54-56, 58-68, 70 and 78 are withdrawn from consideration and/or canceled. Applicant reserves the rights to pursue the withdrawn and/or canceled subject matter in a subsequent application. Support for amended claim 44 for reciting "an enzyme selected from the group consisting of Vibrio cholera neuraminidase (VCN), Papain, β-Gal and ConA, a non-virulent Newcastle virus, and a polysaccharide selected from the group consisting of glucomannan, β-(1-->3)-D-linked glucose, sizofiran (SPG), schizophyllan, mannan, lentinan, Su-polysaccharide (Su-Ps) and mannozym" can be found throughout the application and, *inter alia*, in the original claims 45 and 46 and at page 39, line 29 through page 30, line 11 of the present specification. Claims 53, 57 and 71 are amended to conform with the previous amendment of claim 36. Claims 72 and 79 are amended to overcome certain rejections. The above-described amendments do not introduce any new matter into the present application.

Withdrawn rejections and objections

Applicant appreciates the Examiner's withdraw of rejections and objection as set forth in Paper No. 13 that are not repeated in the present Office Action (Paper No. 16).

Priority

The present application claims priority benefit of U.S. Provisional Patent Application Serial No. 60/177,024, filed January 19, 2000, under 35 U.S.C. § 119(e). The priority claim is referenced at page 1, lines 2-5 of the present specification and in the Declaration of the Inventor in response to the Notice to File Missing Parts submitted on August 2, 2001 (Exhibit A). Therefore, applicant fully complies with 35 U.S.C. § 119(e). Applicant requests that the Examiner acknowledges the priority claim under 35 U.S.C. § 119(e) in the next Office communication.

Rejections under 35 U.S.C. § 112

Claim 72 is rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that claim 72 recites "buccal" as a type of neoplasm to be treated. The Examiner alleges that it is unclear what the metes and bounds of the claim encompasses as "bruccal" is not a known tissue type or organ. The Examiner further states that for purpose of examination, bruccal will be read as "buccal".

This rejection is overcome by the replacement of "bruccal" with "buccal" in claim 72.

Claim 79 is rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Examiner alleges that claim 79 recites is indefinite for reciting "cytolytic gene sequence".

This rejection is overcome by the deletion of "cytolytic gene sequence" in claim 79.

Claim 79 is rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, Examiner alleges that claim 79 lacks written description for reciting "cytolytic gene sequence".

This rejection is overcome by the deletion of "cytolytic gene sequence" in claim 79.

Claim 79 is are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods comprising the administration of a cytokine containing depot, does not allegedly provide enablement for methods comprising the administration of a suicide gene sequence, a cytolytic gene sequence, a cytokine gene sequence, a reporter, a reporter gene sequence or a radiation sensitizer.

This rejection is overcome by the deletion of "a suicide gene sequence, a cytolytic gene sequence, a cytokine gene sequence, a radiation sensitizer" and "a reporter and a reporter gene sequence" in claim 79.

Claim 72 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for treating neoplasms consisting of adrenal gland, anus, bile ducts, bladder, bone, breast, b[r]uccal, cervix, colon, ear, endometrium, esophagus, eyelids, fallopian tube, gastrointestinal tract, head and neck, heart, kidney, larynx, liver, lung, mandible, madibular condyle, maxilla, mouth, nasopharynx, nose, oral cavity, ovary, pancreas, parotid gland, penis, pinna, pituitary, prostate gland, rectum, salivary glands, skin, small intestine, stomach, testes, thyroid, tonsil, urethra, uterus, vagina and vulva neoplasm does not allegedly provide enablement for methods of treating neoplasms consisting of auditory nerve, brain, central nervous system, eye, spinal cord and vestibulocochlear nerve.

This rejection is overcome by the deletion of auditory nerve, brain, central nervous system, eye, spinal cord and vestibulocochlear nerve in claim 72.

Claim 44 is rejected under 35 US.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, Examiner alleges that claim 79 lacks written description for reciting "an enzyme, a non-virulent virus, a polysaccharide and a herb extract."

This rejection is overcome by the amendment of claim 44.

Claims 53 and 57 are objected to as being dependent upon a canceled base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

These objections are overcome by the amendments of claim 53 and 57.

CONCLUSION

Applicant submits that the rejections of claims 44, 72 and 79 under 35 U.S.C. § 112 and objections to claims 53 and 57 have been overcome by the above remarks and/or amendments. Early allowance of the pending claims 36, 37, 39, 40, 42-44, 47, 48, 50, 53, 57, 69, 71-77 and 79 are earnestly requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit** Account No. 03-1952 referencing docket no. 494492000100. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 6, 2004

Respectfully submitted,

Peng Chen

Registration No.: 43,543 MORRISON & FOERSTER LLP 3811 Valley Centre Drive, Suite 500 San Diego, California 92130

(858) 720-5117





Docket No.: 494492000100	
Scrial No.: 09/765 060 Atty: Peng Chen	
Title: COMBINATIONS AND METHOD Filing Date: January 17, 2001	
Date of Mailing: AUGUST 2, 2001 VIA FIRST CLASS MAIL	
	i

Papers enclosed:

Transmittal Form - 1 page

Fee Transmittal - 1 page (in duplicate)

Petition for 1 Mo Extension, 1 page (in duplicate)

- Copy of Notice to File Missing Parts of Application -2 pages
- Declaration for Utility Patent Application (executed) 3 pgs Drawings Transmittal, 1 page
- Drawings, 3 pages

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	Applica	tion Number	09/765,060	· CCE	
TRANSMITTAL	Filing C	ate	January 17, 2001	.// .	
FORM	First Na	med Inventor	Baofa YU	TECHOO 2 200	
•	Group	Art Unit	1646	TOH CENTER	
(to be used for all correspondence after initial t	iling) Examir	er Name	To be assigned	TECH CENTER 1600/290	
Total Number Of Pages In This Submission /	4 Attorne	y Docket No.	494492000100		
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Fee Transmittal Form	Assignment (for an Appli	Papers		After Allowance Communication to Group	
Fee Attached -	Drawing(s),	3 sheets		Appeal Communication to Board of Appeals and Interferences	
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CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on August 2, 2003.

Rhea Amid

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PTO/SB/17 (09-00)

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The Act of Trademark Office; Complete if Known **FEE TRANSMITTAL** Application Number 09/765,060 61 FOR FY 2001 **JANUARY 17, 2001** Filing Date Baofa YU First Named Inventor (not yet assigned) Examiner Name Patent fees are subject to annual revision. Group Art Unit (\$)1 006.00 494492000100

TOTAL AMOUNT OF PATMENT						
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103 18 203 9 Claims in excess of 20	'**				(37 CFR § 1.129(a))	
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102 80 202 40 Independent claims in excess of 3	149	710	243	300	examined (37 CFR § 1.129(b))	
104 270 204 135 Multiple dependent claims, if not paid	179	710	279	355	Request for Continued Examination (RCE)	
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SUBMITTED BY					Complete (if applicable)	
Now (Distance) Perso Chan	Re	gistration N	lo.	43,543	Telephone (858) 72	0-5117

Name (Print/Type) Peng Chen (Attorney/Agent) Date **AUGUST 2, 2001** Signature

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number. 494492000100

U.S. Patr

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In re Application of Baofa YU

Application Number

09/765,060

Filed

COMBINATIONS AND METHODS FOR TREAT

NEOPLASMS

Group Art Unit 1646

To be assigned

HOELER 160GESOO This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time per	iod desired):
☑ One month (37 CFR 1.17(a)(1))	\$ <u>55.00</u> .
☐ Two months (37 CFR 1.17(a)(2))	\$
☐ Three months (37 CFR 1.17(a)(3))	\$
Four months (37 CFR 1.17(a)(4))	\$
Five months (37 CFR 1.17(a)(5))	\$
Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee are reduced by one-half, and the resulting fee is: \$55. A check in the amount of the fee is enclosed.	nount shown above is
 ☐ Payment by credit card. Form PTO-2038 is attached. ☐ The Commissioner is authorized to charge the above fees to Deposit Account 	Number 03-1952 .
The Commissioner is hereby authorized to charge any fees which may be recoverpayment, to Deposit Account Number 03-1952, ref. docket no. 4944920 duplicate copy of this sheet.	quired, or credit any
I am the applicant/inventor	
assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96	5).
attorney or agent of record.	
attorney or agent under 37 CFR 1.34(a). Registration number if acting under 37 CFR 1.34(a) 44,461.	*
WARNING: Information on this form may become public. Credit cabe included on this form. Provide credit card information and aut	rd information should not horization on PTO-2038.
Aug. 2, 25	ignature
PENC	G CHEN (Reg. No. 43,543)
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representat	tive(s) are required. Submit multiple

forms if mor than on signature is required, se below.

forms are submitted. Total of

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COMMISSIONER FOR PATENTS UNITED STATES PATENT AND TRADEMARK OFFICE WASHINGTON, D.C. 20231

www.uspto.gov

APPLICATION NUMBER

FILING/RECEIPT DATE

FIRST NAMED APPLICANT

ATTORNEY DOCKET NUMBER

09/765,060

01/17/2001

Baofa Yu

494492000100

CONFIRMATION NO. 7710

FORMALITIES LETTER

ECH GENTER 1600/2004 *OC000000006032622*

Peng Chen Morrison & Foerster LLP Suite 500 3811 Valley Centre Drive San Diego, CA 92130-2332

Date Mailed: 05/03

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given TWO MONTHS from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- Applicant must submit \$ 355 to complete the basic filing fee and/or file a small entity statement claiming The statutory basic filing fee is missing. such status (37 CFR 1.27).
- Total additional claim fee(s) for this application is \$531.
 - \$531 for 59 total claims over 20.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.
- The balance due by applicant is \$ 951.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Substitute drawings in compliance with 37 CFR 1.84 because:
 - drawing sheets do not have the appropriate margin(s) (see 37 CFR 1.84(g)). Each sheet must include a top margin of at least 2.5 cm. (1 inch), a left side margin of at least 2.5 cm. (1 inch), a right side margin of at least 1.5 cm. (5/8 inch), and a bottom margin of at least 1.0 cm. (3/8 inch);

A copy of this notice <u>MUST</u> be returned with the reply.

Customer Service Center

Initial Patent Examination Division (703) 308-1202
PART 2 - COPY TO BE RETURNED WITH RESPONSE



COMBINED DECLARATION AND POWER OF ATTORNEY FOR UTILITY PATENT APPLICATION

APPLICATION

As stated below next to my name of the claimed to the and for which a patent is sought on the invention entitled: COMBINATIONS AND METHODS FOR TREATING NEOPLASMS, the specification of which is attached hereto unless the following box is checked:

was filed on January 17, 2001, as United States Application Serial No. 09/765,060.

I HEREBY STATE THAT I HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE-IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS. AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE.

I acknowledge the duty to disclose information which is material to the patentability as defined in 37 C.F.R. § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed:

Application No.	Country	Date of Filing (day/month/year)	THOIRY.	Claimed?
*	-		□Yes	□No

I hereby claim benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application Serial No.	Filing Date		
60/177,024	Jan. 19, 2000		

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to

patentability as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

Application Serial No.	Filing Date	Status		
*		□Patented	□Pending	□Abandoned

I hereby appoint the following attorneys and agents to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Laurie A. Axford (Reg No. 35,053) Joseph Barrera (Reg No. 44,522) Shantanu Basu (Reg No. 43,318) Frank P. Becking (Reg No. 42,309) Jonathan Bockman (Reg No. 45,640) Barry E. Bretschneider (Reg No. 28,055) Nicholas Buffinger (Reg No. 39,124) Mark R. Carter (Reg No. 39,131) Peng Chen (Reg No. 43,543) Thomas E. Ciotti (Reg No. 21,013) Matthew M. D'Amore (Reg No. 42,457) Peter Davis (Reg No. 36,119) Carolyn A. Favorito (Reg No. 39,183) Hector Gallegos (Reg No. 40,614) Kenneth R. Glick (Reg No. 28,612) Douglas G. Hodder (Reg No. 41,840) Peter Hsieh (Reg No. P-44,780) Madeline I. Johnston (Reg No. 36,174) Parisa Joriani (Reg No. 46,813) Richard C. Kim (Reg No. 40,046) Kawai Lau (Reg No. 44,461) Lisa E. Marks (Reg No. 44,901) Gladys H. Monroy (Reg No. 32,430) Kate H. Murashige (Reg No. 29,959) Irene T. Pleasure (Reg No. 45,506) Paul J. Riley (Reg No. 38,596) Debra A. Shetka (Reg No. 33,309) Rebecca Shortle (Reg No. 47,083) Stanley H. Thompson (Reg No. 45,160) E. Thomas Wheelock (Reg No. 28,825) Thomas G. Wiseman (Reg No. 35,046) David T. Yang (Reg No. 44,415) George C. Yu (Reg No. 44,418)

Sanjay S. Bagade (Reg No. 42,280) Erwin J. Basinski (Reg No. 34,773) Richard R. Batt (Reg No. 43,485) Vincent J. Belusko (Reg No. 30,820) Kimberly A. Bolin (Reg No. 44,546) Tyler S. Brown (Reg No. 36,465) A. Randall Camacho (Reg No. 46,595) Robert K. Cerpa (Reg No. 39,933) Thomas Chuang (Reg No. P-44,616) Cara M. Coburn (Reg No. 46,631) Raj S. Davé (Reg No. 42,465) Stephen C. Durant (Reg No. 31,506) David L. Fehrman (Reg No. 28,600) Debra J. Glaister (Reg No. 33,888) Johney U. Han (Reg No. 45,565) Charles D. Holland (Reg No. 35,196) Wayne Jaeschke, Jr. (Reg No. 38,503) Richard D. Jordan (Reg No. 33,519) Ararat Kapouytian (Reg No. 40,044) Cameron A. King (Reg No. 41,897) Rimas T. Lukas (Reg No. 46,451) Michael J. Mauriel (Reg No. 44,226) Philip A. Morin (Reg No. P-45,926) Martin M. Noonen (Reg No. 44,264) Catherine M. Polizzi (Reg No. 40,130) Robert Saltzberg (Reg No. 36,910) Terri Shieh-Newton (Reg No. 47,081) Kevin R. Spivak (Reg No. 43,148) Michael R. Ward (Reg No. 38,651) Todd W. Wight (Reg No. 45,218) Frank Wu (Reg No. 41,386) Peter J. Yim (Reg No. 44,417) Karen R. Zachow (Reg No. 46,332)

and:

Please direct all communications to:

Peng Chen Morrison & Foerster LLP 3811 Valley Centre Drive Suite 500 San Diego, California 92130-2332

Please direct all telephone calls to Peng Chen at (858) 720-5117.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name:

Residence:

San Diego, California 92122 USA

Citizenship:

People's Republic of China

Post Office Address:

4443 Governor Drive, San Diego, California 92122 USA

JAN 0 8 2004

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Assistant Commission of the Machine Commission of the Commiss

RHEA AMID

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Baofa YU

Serial No.:

09/765,060

Filing Date:

JANUARY 17, 2001

For:

COMBINATIONS AND METHODS

FOR TREATING NEOPLASMS

Examiner: To Be Assigned

Group Art Unit: 1646

SUBMISSION OF FORMAL DRAWINGS

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Enclosed are THREE (3) sheet(s) of formal drawings in connection with the aboveidentified application.

Respectfully submitted,

Dated:

August 2, 2001

By:

Peng Chen

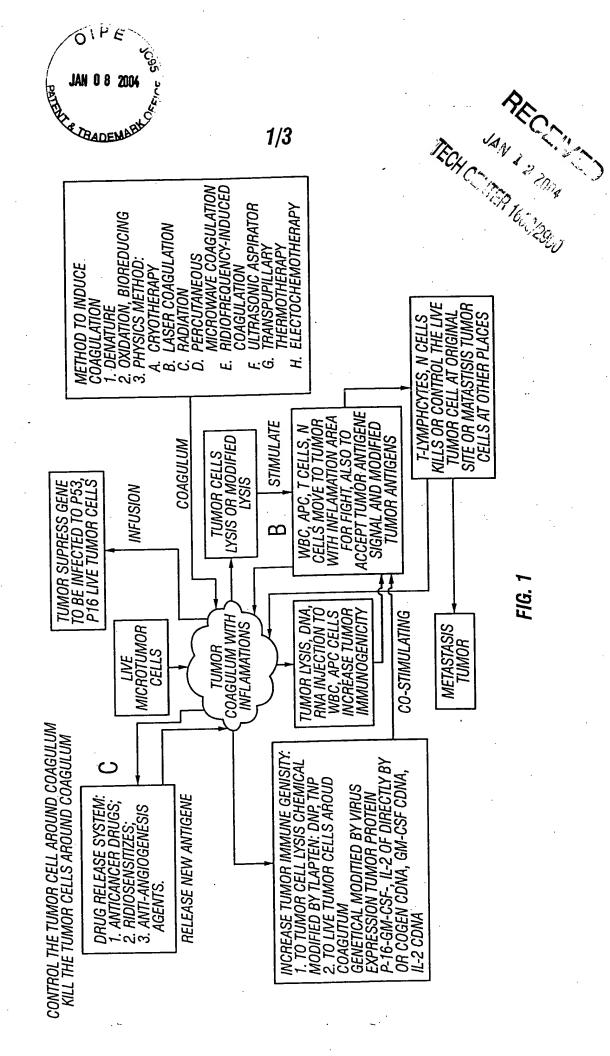
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Telephone: (858) 720-5117 Facsimile: (858) 720-5125



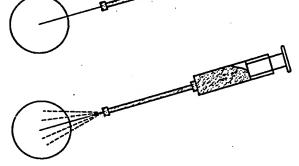


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TECH CENTER ICOLOGO

SPINAL NEEDLE

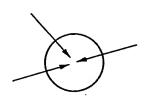
SLOWLY INJECTION



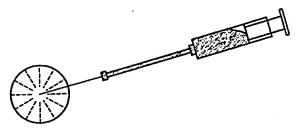
TURNING THE TOP OF NEEDLE, AROUND IN TUMOR



PREPARATION OF INJECTION CHANNELS IN TUMOR BY THE PROBE OF INJECTOR



MULTIPLE INJECTION AT ONE TIME PERIOD INJECTION AT DIFFERENT TIME



HIGH PRESSURE INJECTION BY DILOTION INJECTOR 0-6. AMP AT ONE TIME. HIGH PRESSURE SOLUTION CAN PENETRATE INTO AN EXTRACELLULAR MATRIX BETWEEN TUMOR CELLS

